

The runaway defibrillator...A case of an implantable cardioverter-defibrillator that failed communication and deactivation with a magnet



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Introduction

Implantable cardioverter-defibrillators (ICDs) are indicated for the primary prevention of sudden cardiac death in patients with systolic heart failure defined as left ventricular ejection fraction $\leq 35\%$ and on optimal medical management.¹

There are 4 major ICD functions:²

1. Sensing (recognition of local atrial and ventricular electrogram signals).²
2. Detection (classification of sensed signal according to programmable heart rate zones).²
3. Provision of therapy to terminate ventricular tachycardia or ventricular fibrillation.²
4. Pacing for bradycardia and/or cardiac resynchronization therapy.²

We describe an extremely rare case of an ICD malfunction during a routine check-up initiated by wireless interrogation and triggering inappropriate shocks delivered in sinus rhythm, not suppressed by direct magnet application.

Case presentation

A 60-year-old man presented to our institution's device clinic for routine evaluation of his ICD. He received his first ICD in 2002 for primary prevention in the setting of ischemic cardiomyopathy. He had had a generator change to a St Jude Medical Fortify Assura VR, model CD1257-40 in September 2012 without any complications. Two months later, he had an interrogation, which showed normal ICD function, normal thresholds, and normal battery status. There were no arrhythmias or therapies delivered.

KEYWORDS Implantable cardioverter-defibrillator; Inappropriate ICD shocks; Runaway defibrillator; Heart failure; Device interrogation

ABBREVIATIONS EP = electrophysiology; ICD = implantable cardioverter-defibrillator (Heart Rhythm Case Reports 2016;2:40–42)

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The patient presented 6 months later for routine device evaluation. Upon wireless interrogation, all communication with the ICD was lost. During attempts to communicate with the ICD using multiple programmers, wirelessly and via wand, the patient experienced multiple shocks documented via electrocardiogram telemetry to be inappropriate. Multiple magnet applications failed to deactivate the ICD and the patient continued to receive inappropriate shocks.

The patient was taken urgently to the electrophysiology (EP) lab for evaluation of lead integrity and emergent generator extraction and exchange. During the procedure, the patient continued to receive multiple shocks while in sinus rhythm (Figure 1). The lead, which was a Guidant Boston Scientific model number 0148 Endotak Reliance implanted in 2002, was examined under fluoroscopy (Figure 2, and video 1, available online), which showed normal position, and via pacing system analyzer, which showed normal impedance of 560 ohms, normal sensing of more than 12 mV, and normal threshold of 1.25 V at 0.5 milliseconds. A new generator was placed and connected to the chronic lead. Evaluation of the new generator showed normal function with cessation of inappropriate shocks. The patient recovered uneventfully and was discharged the next day.

The faulty generator was sent to St Jude Medical for analysis per protocol to determine the cause of this malfunction. This case was also reported to the US Food and Drug Administration.

To our knowledge, this is the first case report of a “runaway defibrillator” we define as an ICD delivering high-energy, inappropriate shocks in normal sinus rhythm, and that is unable to be communicated with or deactivated with magnet application. This, apparently, was triggered by an initial wireless communication attempt. St Jude Medical did an extensive analysis and after several months reported back with the conclusion that “*The reported field event was caused by a Power on Reset (POR), however the device image was corrupt and no further information could be gathered. The failure mechanism that caused the POR also caused a telemetry anomaly and high current drain on the hybrid. The failure mechanism was lost during bench testing.*”

KEY TEACHING POINTS

- Inappropriate implantable cardioverter-defibrillator (ICD) shocks can be caused by supraventricular tachycardias, electromagnetic interference, lead failure, or oversensing T waves.
- Prompt replacement or explantation of an ICD should be performed when conventional methods of troubleshooting fail, and when the patient's safety is compromised.
- Patients with cardiac devices should always have quick and easy access to advanced cardiac care in case of emergencies.
- Devices are becoming more sophisticated and companies manufacturing them should provide appropriate support and troubleshooting options for physicians implanting these devices.

The root cause of the field events was an intermittent circuit failure; the location of which could not be determined."

Discussion

The differential diagnosis of multiple ICD shocks, whether appropriate or inappropriate, is broad and is summarized in Table 1. Our case does not fit any of these scenarios and differentials. An important maneuver when dealing with inappropriate ICD shocks is magnet application. A St Jude Medical device can be programmed to either ignore the magnet or respond by turning off both sensing and antitachycardia therapies. In our case, the patient's device was previously programmed to respond by inhibiting sensing and therapies.

In our particular case, there were no presenting arrhythmias, either ventricular or supraventricular (Figure 1); there were no separate pacing systems that could interact; and there was no electromagnetic interference, since the patient received shocks in 3 different places (device clinic, our observation unit, and EP lab). Lead failure due to fracture or insulation break is a far more common cause of inappropriate shocks than generator failure. The lead, however, was intact and its function was within normal limits when tested with the new generator. Magnet application should have inhibited any therapies in the case of a possible oversensing scenario. The company's report concluded that the source of the problem was the generator indeed, but the company was not able to determine the root cause of its malfunction. It also remains unclear if this was triggered by the process of wireless interrogation or if this was a pure coincidence. There are 2 previous cases reported in the literature about pulse generator failures. The first one was by Carpenter et al³ in 1998, in which they reported a generator that was constantly pacing despite the placement of a magnet and turning its functions off. The cause was later identified as an oscillator failure. The second case, by Zaim et al⁴ in 2002, was that of a generator that was delivering continuous ventricular pacing and for which treatment was also to change the generator. However, the circumstances of that case were unclear, as the patient presented to the emergency room with chest discomfort. He was also never shocked, and his device failed to deliver therapy in response to ventricular fibrillation induced by the device itself.

The team exhausted all possible solutions before deciding to take the patient to the EP lab. In the case of our "runaway defibrillator," the only solution was to do an emergency intervention with generator replacement.

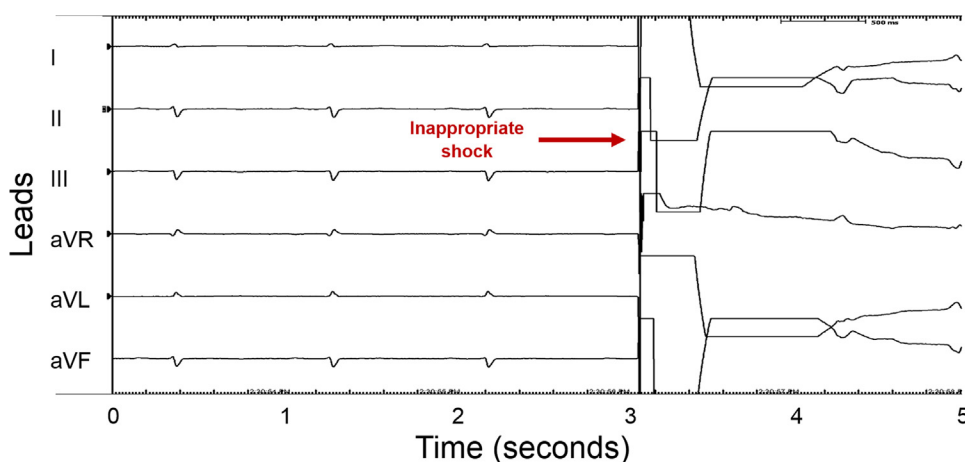


Figure 1 Inappropriate shock delivered in normal sinus rhythm.

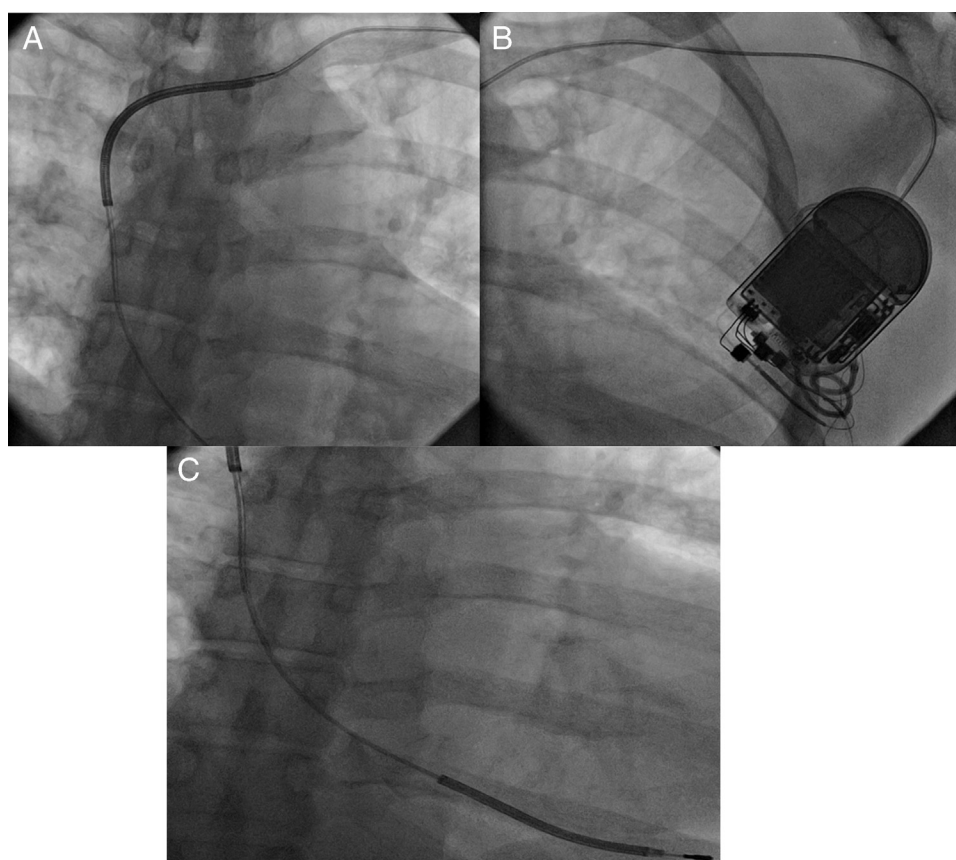


Figure 2 A, B, C: Still images of the cine loop taken for the lead to examine its integrity before changing the generator. The lead appears intact.

Table 1 Common causes of implantable cardioverter-defibrillator shocks

Appropriate shocks	Inappropriate shocks
Ventricular fibrillation	Supraventricular arrhythmias
Ventricular tachycardia	Oversensing T waves
Torsades de pointe	Lead failure or insulation break
	Electromagnetic interference
	Oversensing another pacing system

Conclusions

Manufacturing companies of highly technical and sophisticated devices that revolutionized the world of electrophysiology and medicine should continue to work hard on ensuring the safety of their devices and make solutions available to deal with situations like this. Highly trained physicians and centers capable of addressing these issues with appropriate urgency must be available for patients who receive such devices.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at <http://dx.doi.org/10.1016/j.hrcr.2015.09.001>.

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